APPENDIX 1 (CORRECTED)

HSIA halogenated solvents industry alliance, inc.

MEMORANDUM

To: Docket EPA-HQ-OPPT-2016-0163

From: Faye Graul
Executive Director

Date: March 16, 2017

Subj: Trichloroethylene Drinking Water Study

Attached please find a copy of Protocol Number WIL-459501 titled An Oral (Drinking Water) Study of the Effects of Trichloroethylene (TCE) on Fetal Heart Development in Sprague Dawley Rats. The Protocol was signed on October 6, 2016 and the in-life portion of the study was conducted during October and November, 2016. Unfortunately, the concentrations of TCE measured in the drinking water solutions were found to be below the acceptable target range of 100% ± 10%, invalidating the study. The laboratory is conducting additional studies to identify the source of the deviations and the study will be rerun as soon as the dosing methodological issues are resolved and scheduling permits.

3033 Wilson Boulevard, Suite 700 • Arlington, VA 22201
www.hsia.org

WIL RESEARCH

5 August 2016
Proposal: 15.04279

Proposal for Halogenated Solvents Industry Alliance

Proposal provided by:
WIL Research
1407 George Road
Ashland, OH 44805
USA
Tel: 419-289-8700
Fax: 419-289-3650
www.wilresearch.com

Contact information:
Brad Haynes, MBA
Business Development Director
Tel: 440-596-9993
E-mail: brad.haynes@wilresearch.com

Eddie Sloter, PhD
Scientific Director
Tel: 419-282-6941
E-mail: eddie.sloter@wilresearch.com

Proposal Summary

Study	Base Study Fee	Optional			Total Study Fee	
		AC	BioAC	TK Report		Authorized
A (5-Group) Prenatal Developmental Toxicity Study of TCE Administered by Drinking Water in Sprague Dawley Rats	$168,000	$12,400	$15,730	$4,100	$200,230	☒
Analytical Validation, Homogeneity, and Stability Study of the Analyte in Aqueous Formulations	$24,160	-	-	-	$24,160	☒
Development and Testing of an LC-MS/MS Method for the Quantification of Test Article (TCE) and a Major Metabolite (TCA) in Rat Plasma	$11,050	-	-	-	$11,050	☒
Validation of an LC-MS/MS Method for the Quantification of Test Article in Rat Plasma	$28,750	-	-	-	$28,750	☒

***Fee and Payment Schedules are subject to credit approval.**

Authorization Statement

Halogenated Solvents Industry Alliance ("Sponsor") hereby awards the above described proposal (the "Proposal") to WIL Research Laboratories, LLC ("WIL") (each a "Party"), and requests WIL to proceed with the necessary activities to initiate these Services, including but not limited to, Protocol development, Study room reservation, and definitive scheduling of Services.

This Proposal, the performance of Services, and each Party's obligations herein are governed by and subject to the WIL Research Laboratories LLC General Terms and Conditions attached hereto (the "General Terms and Conditions"). The General Terms and Conditions are hereby incorporated by reference to this Proposal in their entirety. By executing below, Sponsor acknowledges and represents, and the undersigned person executing this Proposal on behalf of Sponsor certifies, that such person has read and Sponsor agrees to the provisions set forth in the General Terms and Conditions.

This Proposal (including the relevant Protocol), together with the General Terms and Conditions and the Confidentiality Agreement between the Parties dated [08/08/16], constitutes the entire agreement (the "Agreement") between the Parties with respect to the subject matter contained herein. There are no oral or written promises, terms, conditions, or obligations other than those contained in this Agreement. This Agreement supersedes all prior negotiations, representations or other agreements, either written or oral, between the Parties on the subject matter related herein. No modification or waiver of the provisions of this Proposal, the General Terms and Conditions or the Confidentiality Agreement shall be valid or binding on either Party unless agreed to in writing by each Party.

In the event the terms of this Proposal or any other agreement between the parties hereto contradict any provision of the General Terms and Conditions, the General Terms and Conditions shall control unless expressly agreed to in writing by each Party herein.

Any notices given hereunder shall be sent by fax or email, with a confirmation copy sent via overnight courier to the following addresses (or such other address as a party may designate as a notice address in a written notice to the other party) and shall be deemed received when delivered (or if received on a weekend or holiday, on the next business day thereafter) as follows:

If to Sponsor: Name: John Bell
Title: Director, Scientific Programs
Company: Halogenated Solvents Industry Alliance, Inc.
Address: 3033 Wilson Boulevard
Suite 700
Arlington, VA 22201
Phone: 202-286-6464
Email: jbell@hsia.org

If to WIL: John Maxwell
Vice President
WIL Research Laboratories, LLC
1407 George Road
Ashland, OH 44805
Phone: (419) 289-8700
Email: john.maxwell@wilresearch.com

With a copy to: Corporate Counsel
WIL Research Laboratories, LLC
8025 Lamon Avenue
Skokie, IL 60077
Email: jon.galli@wilresearch.com

By executing this document Sponsor understands, acknowledges and agrees to the financial responsibility for all costs and expenses in accordance with this Proposal including those incurred by WIL in preparation of the Study. Any modification that requires an increase in cost subsequent from the effective date of this Proposal will be adjusted through a Study Modification.

J v Bell

Signature of Authorized Sponsor Representative

August 8, 2016
Date

Name: John Bell, Ph.D., DABT

Title: Director, Scientific Programs

Company: Halogenated Solvents Industry Alliance, Inc.

Company Address: Suite 700

3033 Wilson Boulevard

Arlington, VA 22201

Email Address (invoices will only be sent as a PDF to this email address):

jbell@hsia.org

A (5-Group) Prenatal Developmental Toxicity Study of TCE Administered by Drinking Water in Sprague Dawley Rats
Compliance: GLP, OECD
Guidelines: Modified OECD 414

Group	Toxicology Animals (145)	
	Toxicology Females (150)	Maternal TK (20)
1	25	4
2	25	4
3	25	4
4	25	4
5	25	4
6	25	-

Objective: To detect potential adverse effects on the pregnant female and on the development of the embryo and fetus consequent to exposure of the female starting the day after mating (Gestation Day 1) through implantation and gestation until one day prior to expected parturition.

Animals[2]: Female Sprague Dawley Rats Crl:CD(SD)
170 animals on study, 212 animals ordered

Untreated sexually mature males of the same strain and source will be used to induce pregnancies.

Groups: 1 control group, 4 test article-treated groups and 1 positive control group.

Dose Levels[3]: Highest dose will be 1100 ppm in drinking water based on a previous study conducted by Johnson et al.

Test Substance Preparation: Prepared at a frequency consistent with established stability.

Sampling of Formulations: From the first and last preparations. Samples analyzed at WIL Research (optional).

Test Substance Administration: Via drinking water (glass water bottles) from gestation day 1 until the day of scheduled necropsy at the end of gestation, inclusively. Day evidence of mating is confirmed is gestation day 0.

Group 6 (positive control group) dosed via oral gavage from Gestation Day 6-15, inclusively.

Viability Observations: Twice daily observations for moribundity and mortality.

Clinical Observations: Once daily.

Body Weights: Toxicology Animals: Gestation days 0-20 (daily).

Toxicokinetic Animals: Gestation days 0-20 (daily).

Food Consumption: Toxicology Animals: Gestation days 0-20 (daily).

Toxicokinetic Animals: Not recorded.

Toxicokinetics: Maternal TK Phase – Blood samples collected from each dam on GD 8, GD 16 and again at the end of the administration period (GD 20) from 4 maternal toxicokinetic animals/group/time point at a single time point (60 maternal samples). Samples can be analyzed at WIL Research (optional).

Fetal TK – Immediately following the final maternal tk blood collection on GD 20, each dam will be euthanized and fetal blood will be collected from the umbilical vessel of each fetus and pooled by litter (20 pooled fetal samples). Samples can be analyzed at WIL Research (optional).

Scheduled Laparohysterectomy: Toxicokinetic Animals: Gestation day 20; Determination of pregnancy status only and fetal blood collected as required.

Toxicology Animals: Gestation day 20; Examination of uterine contents: determination of pregnancy status, gravid uterine weights, gross evaluation

of placenta and count of corpora lutea, implantation sites, early and late resorptions and viable and nonviable fetuses.

Fetal Observations: External and fresh visceral examinations of all viable fetuses for developmental variations and malformations, sex ratios and body weights. The carcass of each fetus will be preserved and retained for possible future skeletal evaluation.

Quality Assurance: The study will be conducted in compliance with Good Laboratory Practice (GLP) standards and will be monitored by the Quality Assurance Unit.

Reports: Audited Draft Report and Final Report.

Archiving: For a period of six months after study completion.

5-Group Base Study Fee (Full Fetal Visceral Evaluations) [1] $168,000

Optional Support Fees:

Analytical Chemistry (AC): [2] $3,400/set

Concentration determination (1st preparation with concurrent homogeneity):	$3,400
Resuspension homogeneity (1 interval):	$3,400
Concentration determination (last preparation):	$3,400
Sample analysis report:	$2,200
Total Study-specific AC:	$12,400

Bioanalytical Chemistry (BioAC): [4]

Sample analysis - 80 samples @ $85/sample (minimum batch 100 samples):	$8,500
Dilution repeats - 30 samples @ $85/sample[5] (estimated 10% of samples; minimum batch 30 samples):	$2,550
Incurred sample reanalysis - 8 samples @ $85/sample:	$680
Report Fee[6]:	$4,000
Total Study-specific BioAC:	$15,730

Toxicokinetic Report:

Preparation of a toxicokinetic report from the maternal and fetal exposure data for a single analyte and single dose route. Preliminary toxicokinetic results will be available upon request and will typically be provided within two business days of availability of bioanalytical data.

TK Report: $4,100

1. Final price depends on the technical details in the final protocol and will be set forth in a Work Order. Base study fee is exclusive of analytical and bioanalytical chemistry support and toxicokinetic evaluation. This quotation is valid for 90 days with respect to authorization of the study, provided the study is initiated within six months from the date of this outline; thereafter the study fee is subject to review.
2. A minimum of 20 litters per group is recommended in this guideline.
3. Studies that do not establish a maternal NOAEL may be acceptable under this guideline.
4. These fees are considered estimates until the method has been developed. The fee for method development and validation is not included. Upon completion of the method development, the sponsor will be notified if different analysis fees apply. The costs also assume typical sample processing as well as standard analytical detection will be sufficient. Long processing procedures, long analytical run times, and mass spectrometric detection will result in an increased fee.
5. These fees are considered estimates. Additional samples and dilution repeats beyond 10% will be charged at a rate of $85/sample. The Sponsor will be notified in writing, prior to application of any such fees.
6. A report fee will be waived if there are ≥ 150 samples analyzed.

Fee and Payment Schedule:
20% upon signature of the Proposal
40% 45 days prior to animal arrival
30% upon completion of in-life
10% upon issuance of Draft Report

Sponsor Number:_____

Study Monitor/ Company Contact: _____ Purchase Order No. (if applicable):_____

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Analytical Validation, Homogeneity, and Stability Study of the Analyte in Aqueous Formulations
Compliance: GLP

Development and validation of a method for the determination of analyte concentration in aqueous formulations:

Method development usually includes (but is not limited to) the following activities: (1) investigation of potential solubility limitations; (2) the analysis of standards prepared in an appropriate solvent to establish chromatography, including retention times, resolution, and to check proportionality of response; (3) the analysis of the analyte prepared in the matrix to confirm the presence or absence of interferences, to evaluate potential stability limitations, and to evaluate response proportionality. Method development will be billed at a rate of $260/hour and will not exceed the amount proposed without sponsor approval.

Validation will be conducted using the current WIL SOP guidelines for the assessment of system suitability, method specificity/selectivity, intra- and inter-session method calibration acceptability, intra- and inter-session method accuracy and precision, ruggedness, and processed sample stability. A minimum of three validation sessions will be conducted. All laboratory work associated with validations will be conducted in accordance with applicable GLP regulations.

Homogeneity and stability assessment of analyte in aqueous formulations:

Testing includes the assessment of test article homogeneity in formulations spanning the range of concentration anticipated on future studies. In addition, resuspension homogeneity and stability will be assessed following a single storage duration. Additional stability time-points can be added for an additional fee. All laboratory work associated with sample analysis will be conducted in accordance with applicable GLP regulations.

Quality Assurance: The study will be conducted in compliance with Good Laboratory Practice (GLP) standards and will be monitored by the Quality Assurance Unit.

Reports: Audited Draft Report and Final Report.

Archiving: For a period of six months after study completion.

Summary of Fees:

Method Development (up to 16 hours):	$4,160
Method Validation in Aqueous Formulations: [2]	$11,000
Homogeneity and Stability Assessments in Aqueous Formulations: [2]	$6,800
Analytical Report:	$2,200
Base Fee [1]	$24,160

1. Final price depends on the technical details in the final protocol and will be set forth in a Work Order. This quotation is valid for 90 days with respect to authorization of the study, provided the study is initiated within six months from the date of this outline; thereafter the study fee is subject to review.
2. These fees are considered estimates until the method has been developed. Upon completion of the method development, the sponsor will be notified if different analysis fees apply. The costs also assume that typical sample processing as well as standard analytical detection will be sufficient. Long processing procedures, long analytical run times, and mass spectrometric detection will result in an increased fee.

Fee and Payment Schedule:
50% upon signature of the Proposal
40% upon completion of analysis
10% upon issuance of Draft Report

Sponsor Number:_____

Study Monitor/ Company Contact: _____ Purchase Order No. (if applicable):_____

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Development and Testing of an LC-MS/MS Method for the Quantification of Test Article (TCE) and a Major Metabolite (TCA) in Rat Plasma
Compliance: Non-GLP

Development:	A fit-for-purpose LC-MS/MS method will be developed for the quantification of test article and one major metabolite in rat plasma. Appropriate chromatographic, mass spectrometric, and sample extraction procedures will be developed to achieve the sensitivity and specifications needed to support non-clinical studies of the test article.
Testing:	Once a suitable method has been developed, testing will be conducted that will include quantifying standards, quality control samples, and blanks to estimate the sensitivity, linearity, accuracy, and reproducibility of the procedure, and to ensure that the proper concentration range and conditions are selected prior to validation or analysis of study samples (as applicable). WIL Research will provide the Sponsor with timely updates on progress.
Quality Assurance:	The study will not be monitored or audited by the Quality Assurance Unit.
Archiving:	For a period of six months after study completion.

Summary of Fees:

Development and Testing [1,2,3]:

24 hours @ $270/hour:	$6,480
Pre-Validation Testing 16 hours @ $270/hour:	$4,320
Materials:	$250
Base Study Fee [4]	$11,050

1. Method development and pre-validation will be billed at a rate of $270/hr. These activities will not be audited.
2. Species-specific plasma will be purchased from commercial sources and will be used as the blank (control) matrix. Estimated cost includes up to 100 mL of rat plasma.
3. The Sponsor will supply or reimburse for the test article(s) and suitable internal standard(s) (all with % purity ≥ 98%). Surcharges may apply for supplies that run outside the normal budget for this work.
4. Final price depends on the technical challenges encountered; additional time beyond that estimated above may be required; the Sponsor will be contacted for approval of any additional work. This quotation is valid for 90 days with respect to authorization of the study, provided the study is initiated within six months from the date of this outline; thereafter the study fee is subject to review.

Fee and Payment Schedule:
50% upon signature of the Proposal
50% upon completion of analysis

Sponsor Number:_____

Study Monitor/ Company Contact: _____ Purchase Order No. (if applicable):_____

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Validation of an LC-MS/MS Method for the Quantification of Test Article in Rat Plasma
Compliance: GLP

Validation:	Validation will be performed according to the FDA "Guidelines for Bioanalytical Method Validation" and 21 CFR Part 58, Good Laboratory Practice for Non-Clinical Laboratory Studies (revised as of April 1, 2007). Testing will include a minimum of 3 runs of matrix standard curves, along with at least 4 QC concentrations (LLOQ, low, medium, high) and at least 18 replicates total at each concentration. Intra-assay and inter-assay precision and accuracy of the QC samples will be determined. Validation will also include evaluation of linearity and limit of quantification, reproducibility, dilution effect, recovery, selectivity, carryover and processing, freeze-thaw, whole blood, and stock solution stability.
Stability:	All plasma stability evaluations will be performed at the low, high, and dilution QC levels. Long-term frozen storage stability testing at one time point and at one temperature is included in the validation fee.
Additional Fees:	Additional fees, $4,500/occasion, may be applied if additional stability time points/temperatures are requested by the Sponsor.
Protocol:	A protocol will be prepared by WIL Research for the validation. The Sponsor and/or Sponsor's representative will review the draft protocol and approve the final protocol.
Quality Assurance:	The study will be conducted in compliance with Good Laboratory Practice (GLP) standards and will be monitored by the Quality Assurance Unit.
Reports:	An audited draft validation report will be prepared by WIL Research and the Sponsor will be given time to review and comment on the report before it is finalized. The final bioanalytical procedure will be provided with the validation report. Requests for specific formatting for protocols and/or reports or multiple revisions may incur additional fees.
Archiving:	For a period of six months after study completion.

Summary of Fees:

Validation for Quantification [1,2,3]

Validation:	$28,000
Additional stability time points @ $4,500/time point:	TBD
Materials:	$750
Base Study Fee [4]	$28,750

1. The validation fee assumes quantification of a single analyte and is considered an estimate until the method has been developed. Upon completion of the method development, the sponsor will be notified if the base study fee will change. The final validation fee is dependent upon, but not limited to the suitability of the IS compound, LC run time, complexity and number of extractions, and other compound-specific issues.
2. Species-specific plasma will be purchased from commercial sources and will be used as the blank (control) matrix for assay validation and stability assessments as well as calibration and quality control sample preparation. Estimated cost includes up to 300 mL of rat plasma.
3. The Sponsor will supply or reimburse for the test article(s) and suitable internal standard(s) (all with % purity ≥ 98%). Surcharges may apply for supplies that run outside the normal budget for this work.
4. Final price depends on the technical details in the final protocol and will be set forth in a Work Order. This quotation is valid for 90 days with respect to authorization of the study, provided the study is initiated within six months from the date of this outline; thereafter the study fee is subject to review.

Fee and Payment Schedule:
50% upon signature of the Proposal
40% upon completion of analysis
10% upon issuance of Draft Report

Sponsor Number:_____

Study Monitor/ Company Contact: _____ Purchase Order No. (if applicable):_____

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WIL Research Laboratories LLC General Terms and Conditions

1. SERVICES AND COMPLIANCE. WIL will use commercially reasonable efforts to perform specific authorized services or studies ("Services") as set forth in the Proposal. WIL will comply with all laws, rules and regulations (collectively, "Laws") applicable to the Services performed. If any Laws change while Services are being performed, and such Laws, in WIL's reasonable judgment, necessitate a change in the Proposal, (a) WIL will submit to Sponsor a revised Proposal for Sponsor's review and acceptance prior to making any changes to Services and (b) WIL will not be required to perform any Service to the extent such performance would, in WIL's reasonable judgment, be in violation of a Law. In the event of a conflict between any applicable Laws, the Parties will mutually agree in writing as to the applicable Laws to be followed in WIL's performance of the Services. Sponsor will comply fully with all Laws applicable to the subject matter of the Services. Notwithstanding anything to the contrary contained herein, WIL may use one or more of its affiliates to perform the Services.

2. MODIFICATIONS. Sponsor will provide to WIL in writing any requested change to Services, and no such request, change, extension, revision or other modification to the Services or any Proposal will be binding unless agreed to in writing by the Parties.

3. COMPENSATION. The amount of all fees and expenses associated with the delivery to Sponsor of the Services are set forth in the Proposal. Sponsor will bear all taxes, fees and expenses other than those set forth in the Proposal. Invoices will be rendered in United States Dollars and provide for payment net 30 days. All invoices will be sent to Sponsor's address indicated in the Proposal, unless otherwise agreed to in writing by the Parties. WIL may request to increase the fees or expenses set forth in the Proposal to reflect any actual increase to its expenses incurred in connection with providing the Services. No such increase will be binding until consented to in writing by Sponsor, which such consent will not be unreasonably withheld. If Sponsor fails to pay an invoice within 45 days of its issuance date, WIL may, in its sole discretion, charge the Sponsor a late fee equal to 1.5% per month on the unpaid balance of such invoice until paid in full (including any assessed late fees) or treat such non-payment as notice by Sponsor to terminate the Services.

4. TERMINATION. (a) A Proposal or specific Services may be terminated as follows: (i) Sponsor may, at any time upon written notice to WIL, terminate the Proposal or specific Services for convenience. Such written notice must state the extent and the effective date of termination. Upon receipt of such notice, WIL will use commercially reasonable efforts to minimize costs to Sponsor resulting from such termination. (ii) WIL may terminate a Proposal or specific Services upon notice to Sponsor of Sponsor's breach or failure to perform any obligations required by this Agreement, including Sponsor's failure to cure payment default within 45 days of invoice issuance. (iii) Either Party may terminate any Proposal upon 90 days' prior written notice to the other Party. (iv) either Party may terminate a Proposal or specific Services upon 30 days written notice if any episode of force majeure described in Section 10 continues for 30 or more days after notification from the other Party of such episode. (b) If Services or Proposal are terminated for any reason pursuant to this Section 4, Sponsor will pay to WIL: (i) all amounts for authorized Services rendered through the effective date of termination; (ii) all wind-down costs incurred by WIL resulting from such termination; and (iii) all of WIL's costs and expenses incurred in preparation for providing the Services, including those incurred prior to commencement of authorized Services and whether invoiced or not. (c) Sponsor may, at any time upon written notice to WIL, delay authorized Services. Sponsor will pay WIL's costs and expenses incurred related to any such delay, and WIL will use commercially reasonable efforts to mitigate such costs and expenses until WIL receives written notice to resume performance of Services. (d) These General Terms and Conditions will apply to any Services performed pursuant to the Proposal, notwithstanding that the Proposal has been terminated, and will terminate upon completion of all outstanding Services, unless otherwise agreed to in writing by the Parties.

5. SURVIVAL. Notwithstanding the termination of the Proposal or specific Services thereunder, Sections 3 (Compensation), 4 (Termination), 5 (Survival), 6 (Intellectual Property & Work Product), 9 (Indemnification & Limiting Liability), 11 (Governing Law & Jurisdiction) and 13 (Miscellaneous) of these General Terms and Conditions will survive, unless otherwise agreed to in writing by the Parties.

6. INTELLECTUAL PROPERTY & WORK PRODUCT. Subject to the last sentence of this Section 6, all information or data collected, and all discoveries, inventions or improvements, whether patentable or not, other than WIL IP (as defined below), arising out of the performance of Services and relating to the articles or substances studied or the use thereof will be owned by Sponsor ("Sponsor IP"). At the request and sole expense of Sponsor, WIL will assign to Sponsor any and all of WIL's right, title and interest in Sponsor IP. Sponsor has no property rights in WIL's testing methods, practices, procedures, tests, test apparatus, equipment or information related to the conduct of WIL's business, or any inventions, improvements or developments related thereto ("WIL IP"). As between the Parties, WIL IP is the sole and exclusive property of WIL. Upon payment in full by Sponsor for all amounts invoiced hereunder, all tissues, tissue blocks, specimens, slides, material and data prepared or generated by WIL in the course of performing Services for Sponsor hereunder ("Work Product") will be owned by Sponsor and will be transferred to Sponsor upon its request after payment of such amounts.

7. INDEPENDENT CONTRACTOR. WIL is an independent contractor and that no provision in the Proposal, or any agreement subject to these General Terms and Conditions, will be construed to make WIL an employee, agent or representative of Sponsor, or be deemed to create a partnership or joint venture between the Parties. Neither Party will hold itself out to third persons as purporting to act on behalf of, or serving as the agent of, the other Party.

8. WARRANTY. Other than as specifically set forth in Section 1, WIL makes no representations or warranties concerning the Services.

9. INDEMNIFICATION & LIMITING LIABILITY. WIL will indemnify, defend and hold harmless Sponsor, its directors, officers, equityholders and employees ("Sponsor Indemnitees") from and against all third party loss or damage (including

reasonable attorney fees and expenses) arising from (a) WIL's material breach of this Agreement or (b) WIL's negligence or willful misconduct in the performance of the Services, except to the extent such loss or damage arises from the negligence or willful misconduct of a Sponsor Indemnitee or Sponsor's material breach of the Agreement. Sponsor will indemnify, defend and hold harmless WIL and its affiliates and their respective directors, officers, equityholders and employees ("WIL Indemnitees") from and against all third party loss or damage (including reasonable attorney fees and expenses) arising from (a) Sponsor's material breach of this Agreement, (b) Sponsor's negligence or willful misconduct or (c) Sponsor's use or exploitation of any Sponsor IP, Work Product or Sponsor Confidential Information, except to the extent such loss or damage arises from the negligence or willful misconduct of a WIL Indemnitee or WIL's material breach of this Agreement. Under no circumstances will either Party be liable to the other for any indirect, consequential, punitive, exemplary or special damages, including lost profits or cost of replacement materials. Subject to any limitations on remedies set forth herein, in no event will WIL be liable to Sponsor under this Agreement for any amounts in excess of the amount paid by Sponsor to WIL for Services provided hereunder. If WIL commits a deviation during the performance of Services that causes the results of such Services to be unusable for Sponsor's stated purposes as defined in the relevant Protocol, then at Sponsor's election, WIL will either (i) rerun that part of the Services affected by such deviation or (ii) refund to Sponsor the sums paid WIL as of that date with respect to such Services. The remedies provided in the immediately foregoing sentence are the Sponsor's (and the other Sponsor Indemnitees') sole and exclusive remedy with respect to WIL's deviations in the performance of Services. The remedies provided in this Section 9 are the sole and exclusive remedies available to the Sponsor Indemnitees with respect to any breach of any representation, warranty or agreement in the Proposal, or otherwise in respect of the Services contemplated by the Proposal (whether in contract, tort, strict liability or otherwise).

10. FORCE MAJEURE. Neither Party will be liable for any delay in performing its obligations (other than payment obligations) under the Proposal if its performance is delayed or prevented by acts of God, fire, terrorist acts, explosion, war, riots, strikes, law or any other cause (except financial) beyond such Party's reasonable control, but only to the extent of such disability. If performance required by the Proposal falls during or subsequent to the occurrence of a force majeure event, performance will be deferred for a period of time equal to the period of disability resulting from force majeure.

11. GOVERNING LAW; JURISDICTION. This Agreement will be construed in accordance with and governed by the laws of the State of Ohio (without regard to any choice or conflicts of law rules that would cause the application of the laws of any other jurisdiction). The Parties irrevocably submit to the personal jurisdiction of the state and federal courts of the State of Ohio, and agree that such courts are the appropriate, exclusive and convenient forum for, and will have exclusive jurisdiction over, any action or dispute arising out of this Agreement or relating to any of the Services, and the Parties irrevocably waive any right to claim that such forum is inconvenient. Neither Party will bring suit with respect to any action or dispute arising out of this Agreement or relating to any of the Services in any court or jurisdiction other than the above specified courts. The preceding sentence will not limit the rights of the Parties to obtain execution of a judgment in any other jurisdiction.

12. ASSIGNMENT. The Proposal subject to these General Terms and Conditions, and any performance thereunder, constitutes a personal services contract and may not be assigned by either Party without the express written consent of the other, which consent may not be unreasonably withheld, except that either Party may assign this contract without consent in connection with a transaction resulting in (a) a change of control with respect to such Party or (b) the acquisition of all or substantially all of such Party's assets by such assignee.

13. MISCELLANEOUS. [Insurance] WIL will maintain in full force and effect during the performance of Services, a policy or policies of insurance commensurate with industry standards for services substantially similar to the Services performed by WIL. [Delivery and Transfer] Any materials or Work Product shipped to WIL by Sponsor or a third party, or shipped by WIL to Sponsor or to a third Party, shall be at Sponsors expense. Therefore, Sponsor will pay any shipping or transportation costs and taxes, including any import or export duties, fees, and taxes. All Work Product will be appropriately packaged and labeled pursuant to WIL's standard operating procedures and delivered to a common carrier for shipment. Sponsor will hold WIL harmless from and against all loss or damage or claims of loss or damage to any Work Product during shipment by a common carrier. Sponsor will also pay the insurance premium and will notify WIL, in writing, of its desire to insure shipments at a rate that exceeds the common carrier's standard liability limit. In the event a claim results, Sponsor shall be responsible for substantiating (if required by the insurer) the value of the Work Product and for seeking reimbursement of any loss. [Severability] If a court of competent jurisdiction finds a provision of these General Terms and Conditions, the Proposal, or any agreement between the Parties subject hereto, to be invalid or contrary to public policy, the provisions not so found will remain in effect and binding upon the Parties. The Parties will agree in good faith to replace any invalid or unenforceable provision with a valid and enforceable provision that expresses as closely as possible the intention of the original provision. [Publications] Neither Party will use the name of the other Party or the other Party's employees in any advertising, sales promotional material, or in any publication without such other Party's prior written consent. [Dispute Resolution] The Parties will attempt in good faith to resolve any dispute arising hereunder prior to taking any legal action. If Parties are unable to resolve any such dispute within 30 days, each Party may seek any legal remedy available in accordance with these General Terms and Conditions. Notwithstanding the foregoing, either Party may seek interim legal relief in a court of competent jurisdiction if the other Party's breach of their obligations under any agreement subject hereto would reasonably be expected to cause such Party irreparable harm. [Precedence] No modification or waiver of the provisions of these General Terms and Conditions shall be valid or binding on either Party unless in writing and signed by both Parties. Unless otherwise expressly agreed to in writing by the Parties, in the event a Proposal, Protocol, or any other agreement between the Parties hereto conflict with or contradict these General Terms and Conditions, then these General Terms and Conditions shall control. [Counterparts] Any agreement between the Parties related to the Services (including any Proposal) may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. Signatures

to any agreement between the Parties related to the Services transmitted by facsimile transmission, by electronic mail in "portable document format" (".pdf") or similar form or by any other electronic means (*e.g.* DocuSign) intended to preserve the original graphic and pictorial appearance of a document will have the same effect as physical delivery of the paper document bearing the original signatures, and will be deemed original signatures by both Parties.

[*Remainder of left blank*]

WIL RESEARCH LABORATORIES LLC CANCELLATION AND DELAY POLICY

Timing	Cancellation Fee	Delay Fee
More than 45 days prior to animal arrival.	10% of the total fee under the signed proposal.	No fee.
Less than 45 days prior to animal arrival.	20% of the total fee under the signed proposal, plus Costs Incurred (as defined below).	$2,100 per day for each room utilized
Any time after animal receipt.	50% of the total fee under the signed proposal, plus the cost of any animals ordered under the proposal and any Costs Incurred.	$2,100 per day for each room utilized plus any Costs Incurred.
Non-animal related studies.	Costs Incurred. for study preparation and conduct including but not limited to time and materials related to protocol preparation and protocol activities, instrument set up, study termination, and reporting (if required)	No fee.

- Unless otherwise expressly agreed to in writing by the Parties, the fees and obligations detailed in this policy are in addition to the written terms and conditions, or any other agreement, as may be agreed to by the Parties.
- Actual fees may vary depending on the nature and specifications of the services (*e.g.* Costs Incurred, species, the number of animals involved, unique animal specifications).
- WIL Research Laboratories LLC ("WIL") shall, in good faith, use commercially reasonable efforts to mitigate costs incurred resulting from any cancellation or delay.
- Upon Sponsor's request, WIL shall make a good faith effort to reschedule cancelled or delayed services as close as possible to the requested time frame.
- Cost Incurred may (i) prior to commencement of services include any reasonable costs and expenses related to study preparation, time and materials related to protocol development, (ii) following cancelation or delay include any reasonable costs and expenses related to maintenance of animals or materials, reoccurring costs related to such delay, any reporting (if required), and any wind-down costs resulting from such cancellation or delay (*e.g.* necropsy). Additionally, in each case, if large animals were ordered or used, then Costs Incurred shall also include the cost to maintain such large animals which such cost will not be less than $2,100 per day for each room utilized, for a minimum of 30 days.
- This information is provided at the request of Sponsor and is intended for the sole use of Sponsor in regards to the services provided by WIL. Further, this information is considered confidential and is not to be copied or shared with any third party unless approved in writing by WIL prior to any disclosure.